WHITEPAPER

X-Cal™ Technology for Enhanced Patient Safety and Improved Clinician Efficiency

SUMMARY

- Masimo has implemented a technology called X-Cal in its sensors, cables, and monitors to enhance patient safety and improve clinician efficiency
- X-Cal is designed to address three common factors that can impact measurement accuracy and patient safety due to reliability risks associated with:
    1. Imitation Masimo sensors and cables
    2. Cables and sensors used far beyond their expected life
    3. Third-party reprocessed pulse oximetry sensors
- Masimo offers its customers choices for reducing pollution and waste in our world while also reducing costs

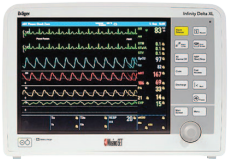
THE TECHNICAL BENEFIT OF X-CAL IS BASED ON MASIMO COMPONENTS WORKING AS AN INTEGRATED SYSTEM

Masimo SET® Measure-through Motion and Low Perfusion pulse oximetry has three system components:

1 Sensor

2 Cable

3 Monitor



Patient Monitor

or

Masimo Oximeter

1) The sensor that connects to the patient
2) The patient cable that connects the sensor to the Masimo circuit board in the monitor
3) The Masimo circuit board (SET® SpO_2 or rainbow® Pulse CO-Oximetry) installed in a multiparameter patient monitor or Masimo Pulse Oximeter®

All Masimo components work together as an integrated system to measure through challenging conditions including motion and low perfusion. When all components are fully functioning, the system works as intended. In contrast, when any of these system components is compromised, erroneous measurements can occur.

PROBLEM #1 ADDRESSED BY X-CAL: POOR QUALITY AND PERFORMANCE OF IMITATION MASIMO SENSORS AND CABLES

Multiple third-party manufacturers have attempted to copy or imitate Masimo sensors and cables. Imitation cables and sensors (also known as "knockoffs", "copy-cat", "pirated" products, etc.) use components without the same design, manufacturing process, or quality controls as Masimo and as such, do not meet Masimo quality or performance specifications. This becomes particularly problematic in challenging conditions.

SOLUTION: When an imitation sensor or cable connects to an X-Cal enabled monitor, a message is displayed to replace the sensor or cable.

PROBLEM #2 ADDRESSED BY X-CAL: RELIABILITY RISKS ASSOCIATED WITH CABLES AND SENSORS WHEN USED BEYOND THEIR EXPECTED LIFE

Eventually, all cables and sensors wear out and fail, and it is widely accepted that the longer any brand of cable or sensor is in service, the more likely that it will reach that point of failure. Masimo is aware of situations in which the monitor has displayed false saturation values because of cable or sensor malfunction or failure. Often, hospital personnel are not aware of the age of a particular cable and the failure is only discovered during active patient monitoring. To avoid these situations and as a matter of policy, some hospitals replace their cables before their expected life is exhausted.

It is also important to note that as cables and sensors become worn, they may also cause intermittent problems with measurement accuracy which lead to false alarms or mask true alarming events such as hypoxemia. Safety recommendations include removing damaged sensors and cables from service for Biomedical Engineering evaluation.[1] Damaged components that lead to intermittent performance issues can cause care inefficiencies and frustration such as repeated returns of the patient cable with intermittent faults to Biomedical Engineering, or repeated, inconclusive biomedical testing and investigation. Given the intermittent nature of the interruption and because the clinical use scenario is not easily replicated, biomedical engineers may find no obvious issue with the cable or sensor and return them to clinical use. This contributes to alarm fatigue for clinicians, which ECRI Institute has rated as the biggest technology issue facing hospitals.[2]

A recent independent study of reusable sensors taken from active use in several hospitals highlights the risk of sensors being used beyond their expected life. The study used a spectrometer to examine 847 pulse oximeter sensors from 29 hospitals. A total of 89 sensors (10.5%) had a functional error of the electrical components that would cause an error in SpO_2 measurement accuracy. The study authors stated: "When undetected, these cable faults frequently cause the monitor to display SpO_2 readings in the low 80s regardless of the patient's true SpO_2 value. These types of cable faults are not identified by the monitor, simulators or standard electrical tests."[3]

Customer feedback indicates that Masimo reusable sensors, cables, and single-patient-use sensors last significantly longer without performance degradation than non-Masimo products. Durability testing and experience through the application of millions of sensors per year demonstrate that Masimo single-patient-use sensors function for about seven days of continuous active use, which is much longer than the average patient stay and well beyond the typical length of monitoring during a patient stay.

SOLUTION: X-Cal provides an automatic method to detect when cables and sensors have been used far beyond their expected life, allowing the aging inventory to be replaced. With X-Cal, biomedical engineers are expected to spend less time troubleshooting faulty/nuisance alarms and even less time investigating, testing, and replacing faulty patient cables.

PROBLEM #3 ADDRESSED BY X-CAL: POOR QUALITY AND PERFORMANCE OF THIRD-PARTY REPROCESSED PULSE OXIMETRY SENSORS

The FDA has stated: "It is essential that users understand that the performance of reprocessed sensors might be different from that of the original sensor."[4] Masimo has found that customers do not always understand how sensors are reprocessed. Customers often assume third-party reprocessed sensors function to the same specification as Masimo sensors. This is not the case. Masimo testing of third-party reprocessed sensors identified a variety of performance issues including biological debris, functional defects, risk of component failure, and adhesive properties that are likely to cause discomfort with infants and neonates.

Third-party reprocessing alters single-patient-use sensors from their original form and function, which may have an adverse effect on the consistency and accuracy of oxygen saturation and pulse rate measurements. Because third party reprocessors do not understand the intricacies of Masimo products, they do not have controls to evaluate the extent of sensor use or condition of components prior
to reprocessing previously used sensors. Consequently, third-party reprocessed sensors often have damage to both optical and electrical components.

Masimo ran multiple tests on sensors produced by a third-party reprocessor (Stryker Sustainability Solutions, formerly Ascent) to evaluate the performance on three important sensor characteristics: light transmission, electrical noise immunity, and sensor adhesion.

- **Light transmission performance:** 91% of the tested sensors did not meet Masimo sensor specifications. Failing this specification means that these sensors could allow light to be read by the detector without passing through the tissues, affecting measured light absorption in a way that could compromise the accuracy of the oxygen saturation measurement.

- **Electrical noise immunity:** 9% of the tested sensors failed electrical noise immunity testing. Electrical noise, such as electro-cautery equipment and exposure to electrostatic discharge (ESD), can cause erroneous readings, intermittent interruptions or sensor failure.

- **Sensor adhesion:** Testing of Infant and Neonatal versions of third-party reprocessed sensors showed that almost three times the pull force was required to remove the sensor compared to Masimo Infant and Neonatal sensors. Single-patient-use sensors need to be removed and reapplied during a patient's hospital stay. Masimo sensors are designed with an adhesive that allows for multiple reapplications and with electrical components that withstand the mechanical forces due to reapplication. At almost three times the pull force to remove the adhesive sensor, third-party reprocessed sensors are likely to cause significant irritation and discomfort to infants and neonates.

In addition, visual quality inspection revealed that 79% of third-party sensors had visible defects, which would not meet Masimo's acceptance criteria. Six percent of third-party sensors had some form of biological debris including hair, skin, and red and yellow stains from bodily fluids. It is unclear what clinical risk is associated with the presence of biological residue in third-party reprocessed sensors, regardless of sterility.

SOLUTION: X-Cal does not prevent the use of reprocessed sensors but does provide an automatic method to detect when reprocessed sensors have been used far beyond their expected life.

HOW X-CAL WORKS

X-Cal is seamlessly integrated into Masimo sensors, cables and circuit boards and is provided at no additional cost to end users. X-Cal can detect imitation cables and sensors and measures the active patient monitoring time of each cable and sensor. Monitors equipped with X-Cal enabled circuit boards will not function with imitation cables and sensors and will display a message to replace cables and sensors that have been used beyond their useful life.

Furthermore, the indication to change a sensor or cable only occurs outside of active patient monitoring to avoid disruption to clinical practice. For example, if the end of a single-patient-use sensor's expected life is reached while actively monitoring a patient, the sensor will continue to operate until monitoring with that sensor is stopped. At the next reapplication of the same sensor, the monitor will display a message to advise the clinician to replace the sensor.

For sensors and patient cables, the active monitoring time limit depends on the sensor or cable, as shown in the table below. For each sensor or cable category, the table below shows the expected life of the sensor or cable, based upon active patient monitoring of 24, 12, or 8 hours per day.

Sensor or Cable	Active Patient Monitoring Limit	Duration if Monitoring 24 Hours Per Day	Duration if Monitoring 12 Hours Per Day	Duration if Monitoring 8 Hours Per Day
Single-patient-use SpO_2 Neo/Adult "L" Sensors	336 hours	14 days	28 days	42 days
Single-patient-use SpO_2 Adult and Pediatric Sensors	168 hours	7 days	14 days	21 days
Reusable SpO_2 Sensors (DCI, DCIP, YI, TC-I, TF-I, and DBI)	8,760 hours	12 months	2 years	3 years
Patient Cables	10,950 hours	15 months	2.5 years	3.75 years

MASIMO OFFERS MULTIPLE OPTIONS TO MAINTAIN SENSOR PERFORMANCE WHILE MAXIMIZING SUSTAINABILITY AND COST-EFFECTIVENESS

Masimo sensor solutions include:

- **Single-patient-use sensors** — Offering performance and convenience, with a replaceable tape option for extended single-patient-use.
- **ReSposable™** — A revolutionary sensor system that offers the performance and comfort of a single-patient-use disposable sensor with unprecedented reduction on carbon footprint and waste. ReSposable offers the green advantages of reusable sensor and a similar sensor price per-patient as using a combination of reprocessed and new single-patient-use sensors.
- **Recycling program for single-patient-use sensors** — For customers who wish to use single-patient-use sensors but recycle, Masimo offers a recycling program in which the sensors can be collected and returned to Masimo so the raw materials can be recycled.
- **Masimo Reprocessing Program for single-patient-use sensors** — For customers who wish to use single-patient-use sensors and reduce costs by reprocessing these sensors without the performance issues of third-party reprocessed sensors, Masimo reprocessed sensors are "rebuilt" by replacing the original emitters, detectors, connecting elements, inner-wrap, and outer adhesive that allows these reprocessed sensors to work as well as new Masimo sensors. Only Masimo reprocessed sensors are validated to perform the same as a new Masimo sensor.

QUESTIONS

If you have any questions on X-Cal, please call 877-932-XCAL or email MasimoTech@masimo.com.

REFERENCES

1 Pennsylvania Patient Safety Advisory. 2(2): 2005:26-29.
2 ECRI Institute. Top Ten Health Technology Hazards for 2012.
3 Milner QJ, Mathews GR. An assessment of the accuracy of pulse oximeters. *Anaesthesia*. 2012.
4 Weininger S. Effective standards and regulatory tools for respiratory gas monitors and pulse oximeters: The role of the engineer and clinician. *Anesth Analg*. 2007:105: S95-99.

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